



Press Release for Immediate Release 25th September 2018

OrthoXel™ Evolving Fracture Fixation Announce FDA 510(k) Clearance
for new Apex Femoral Nailing System

OrthoXel™ is a specialist orthopaedic trauma company, using innovative engineering design to evolve truly next generation fracture fixation devices. OrthoXel™ is delighted to announce that the new Apex Femoral Nailing System has been granted US FDA 510(k) clearance, following regulatory clearances and first clinical implantations of the Apex Tibial Nailing System earlier this year.

The Apex Femoral Nailing System

The Apex Femoral Nailing System features a modern anatomic nail curvature in a universal nail that can be surgically implanted from antegrade or retrograde orientations with a dedicated instrumentation kit. The system offers a comprehensive suite of versatile multiple-trajectory locking options including patented OrthoXel™ micromotion for controlled axial movement with exceptional torsional stability to promote callus formation. Additional locking options include recon and rigid interlocking for unstable proximal femoral fractures.

The unique Apex Femoral Nail locking options provide ultimate flexibility and control for the surgeon to choose the right fixation for each patient. In addition to patented gliding micromotion, the Apex system offers an innovative locking endcap that can simultaneously lock multiple bone screws for added stability when needed.

- **Micromotion Locking:** Up to two mediolateral bone screws and one recon bone screw provide torsional stability with patented controlled axial micromotion.
- **Recon Rigid Locking:** Up to two mediolateral bone screws and two recon bone screws provide rigid locking, with an optional all screw locking endcap.
- **Rigid Interlocking:** Up to two mediolateral bone screws, one recon bone screw, and one interlocking bone screw provide rigid locking. The optional addition of the locking endcap simultaneously locks all four screws when needed.

The OrthoXel™ business focus is on developing the commercial market in the United States for both the Apex Tibial and Femoral Nailing Systems as well as identifying select markets outside the US (OUS). OrthoXel™ is now working to identify potential commercial partners.

Pat O'Connor Co-Founder & CEO, OrthoXel™ – “While we recognise the challenge of entering markets



dominated by large multinationals, OrthoXel™ is confident that the unique locking options and advantageous biomechanics of both our Apex Femoral and our Apex Tibial Nailing Systems confers real market advantage. Our products really should be the devices of choice for orthopaedic trauma care.”

Charles Daly Co-Founder & Chief Technical Officer, OrthoXel™ – “OrthoXel™ is delighted to receive



US FDA 510(k) clearance for the Apex Femoral Nailing System for the specific treatment of a wide range of femoral fractures. We will now be focusing on generating clinical case studies and will be market ready in 2019. Our incredible engineering and design team in Cork has really strived to achieve truly next-generation intramedullary nails that are packed with unique features and benefits for the surgeon and

patient alike. We strongly recommend anyone that wants more detailed product information to visit our new website at www.orthoxel.com.”

About OrthoXel

Founded in 2014, and partially funded under the Enterprise Ireland High Potential Start-Up (HPSU) fund, OrthoXel™ is a specialist orthopaedic trauma device company using innovative engineering design to evolve truly next generation fracture fixation devices.

OrthoXel™ is committed to patient-focused fracture care, offering surgeon-designed devices and an innovative approach to clinical evaluation, from initial concept designs through to full product launch.

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For more information about the technical specification and advanced locking options of the Apex Femoral and the Apex Tibial Nailing Systems visit: www.orthoxel.com/product

Press Contact:

Alanna Carty Global Marketing Manager alanna.carty@orthoxel.com Tel: +353 (0) 86 274 1539